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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,974	BEHNAM, DARIUSH	
	Examiner	Art Unit	
	JOSEPH M.J. HANRAHAN	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/8/07, 3/17/08, 4/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-18, drawn to a composition.

Group 2, claim(s) 19-24, drawn to a method.

2. The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions share a common technical feature in that they both relate to solutions of an active substance with polysorbate. Solutions of polysorbate and active substances are known in the art (Hirsh Col. 2, Lines 26-32). Therefore the claimed subject matter of claim 1 does not provide a contribution over the art, and lack of unity exists.

3. During a telephone conversation with Harvey Jacobson a provisional election was made without traverse to prosecute the invention of Group 1, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

1. The specification is objected to because graphical illustrations, diagrammatic views, flowcharts, and diagrams in the descriptive portion of the specification do not come within the purview of 37 CFR 1.58(a), which permits tables, chemical and mathematical formulas in the specification in lieu of formal drawings. The "specification sheets" that follow the examples in applicant's specification are not permissible. If the applicant wishes to include that information, drawings in accordance with 37 CFR 1.81 should be filed or the information should be tabulated in accordance with 37 CFR 1.58(a).

Claim Objections

2. Claims 7-13 and 15-18 are objected to because the amount of the components listed exceed 100%. It appears from applicant's specification that "%" may have been used instead of "g" (for grams). The examination has been carried out under the assumption that "%" was mistakenly used instead of "g". Appropriate action is required.

3. Claims 1-18 are objected to because the grammar of Claim 1 makes it unclear what, exactly, is intended to be included within the group listed. A semicolon or the statement "and further comprising" following "tea tree oil" would remedy this deficiency.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding Claims 1-18, it is not clear what is “two and a half times the weight of the active substance.” For the purposes of examination the examiner has treated this statement to mean that the polysorbate is present in an amount that is 2.5x the amount of the active substance. Furthermore, it is unclear what is exactly claimed as part of the group. Specifically it is unclear whether polysorbate is to be included in the alternative grouping. Claims 2-17 are rejected on this basis because they depend from Claim 1.

7. Regarding Claims 5 and 6, it is not clear what this claim "consists of" since the transitional phrase is followed by negative limitations. Furthermore, it is unclear whether polysorbate is to be included within the list. This claim can be repaired by putting the limitations into positive terms and properly delineating whether or not polysorbate is to be included within the alternative list.

8. Regarding Claims 1 and 10, Claim 1 recites that the active substance can be “linoleic acid glyceride” and Claim 10 recites "conjugated linoleic acid triglyceride." Therefore, the limitation of Claim 10 lacks a proper antecedent basis. For the purposes of examination, the examiner has read the linoleic acid limitation found in Claim 1 to be a linoleic acid that is not necessarily conjugated.

9. Regarding Claims 11 and 12, the transitional phrase “consisting of" is used which limits the scope of the claim to the recited components. Phosphatidylserine is shown in applicant’s specification to actually be a mixture of phospholipids (data sheets from Degussa). Therefore, it is unclear whether applicant is claiming pure phosphatidylserine or a mixture of phospholipids that includes phosphatidylserine. The examiner has, therefore, treated these claims as though they were written using the transitional phrase "comprised of."

10. Regarding Claim 14, the ratio of 3:7 (2.3333 times) that is presented doesn't fall within the range (at least 2.5 times) disclosed in the parent claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. **Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsh (Us Pat. No. 3052608).** Hirsh teaches a solution of lanolin with an excess of polysorbate that is at least six times the weight of the lanolin (Col. 2, Lines 26-32).

3. **Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Echols (US PG Pub No US 2004/0142038).** Echols teaches an ingredient under the trade name "Amisol Clear" manufactured by DeGussa Chemical (¶ 27). Amisol Clear is a clear solution containing phospholipids, polysorbate 80, glycerin (the examiner treats this as being the same as glycerol) and ethanol. The phospholipids contained in Amisol clear are derived from lecithin. Phosphatidylserine is a specific phospholipid that is derived from lecithin. The phospholipid can be present in amounts as little as 3% and the Polysorbate 80 can be presenting amounts as much as 75% (a 25 fold excess).

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Conklin (US Pat. No. 6444253).

4. Conkilin teaches a composition containing essential oils (Col. 4, Line 11) and polysorbate (Col. 8, Lines 11-15) in a weight ratio of 0.5 to 5 (Col. 3, Lines 64-65).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. **Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsh (US Pat. No. 3052608).** Hirsh teaches the limitations of the claims as described in the 102(b) rejection above. Hirsch fails to teach the exact amounts of the components of the composition. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be

determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have modified the invention taught by Hirsh to give a clear solution of lanolin and polysorbate 80. The motivation to do so would have been to create a clear solution of polysorbate and lanolin that was appropriate for applicant's intended use.

16. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Echols (US PG Pub. No US 2004/0142038) in view of Hirsh (US Pat. No. 3052608).

17. Echols teaches the limitations of the parent claim as described above. In light of the 112 rejection, above, and the specification sheets in applicants' specification, it is not clear that the "consisting of" language of the present claim was used properly and has been interpreted to mean "comprised of". That being said, Claims 11 and 12 contain the same ingredients disclosed in Echols.

18. Echols, however, does not teach the combination of ingredients in the same amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate,

including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Echols with the excess of polysorbate taught by Hirsh to give a clear solution of phosphatidylserine, glycerin, and polysorbate 80. The specific amounts of each ingredient would have been determinable by routine experimentation.

19. Claims 6-8, 10, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conklin (US Pat No. 6444253) as applied to Claim 1 above and further in view of Hirsh.

20. Conklin teaches the limitations of the Claim 1 from which, Claims 6-8, 10, and 13-18 depend. The disclosure of Conklin deals with solutions that are useful as foodstuffs and the disclosure of Hirsh deals with a solutions that are useful in cosmetics. Additionally, both references relate to solutions containing non or partially aqueous ingredients and polysorbate. Since Applicant's invention is directed to solutions containing non or partially aqueous ingredients and polysorbate that are useful as

foodstuffs, cosmetics, and pharmaceuticals (Applicant's specification, Page 1, ¶ 2), both references are considered to be pertinent to the art of the present invention.

21. Regarding Claims 6, 13, and 14, Conklin teaches a solution containing an orange oil type of essential oil (Table 1) and the use of polysorbate 20 as a surfactant (Col. 8, Line 12). Conklin, however, does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a

clear solution of orange oil and polysorbate 20. The specific amounts of each ingredient would have been determinable by routine experimentation.

22. Regarding Claim 7, Conklin teaches that the oils of his invention include ALL "those natural oils normally extracted, as such, from their plant matter or animal source" (Col. 4, Lines 40-45). It would have been obvious to use algae oil as this oil is derived from plant matter, and, as Conklin teaches, any oil derived from plant or animal sources can be used. A known oil, such as algae oil, would be considered obvious given this teaching. Conklin also teaches the use of polysorbate 80 as a surfactant (Col. 11, Ex. 5).

23. Conklin does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective

variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a clear solution of algae oil and polysorbate 80. The specific amounts of each ingredient would have been determinable by routine experimentation.

24. Regarding Claim 8, Conklin teaches that pine oil is contemplated by his invention (Table 1). Pine oil is an excellent source of terpenes, including gamma terpenes. The use of gamma terpenes would have been obvious given this teaching. Conklin also teaches the use of polysorbate 80 as a surfactant (Col. 11, Ex. 5).

25. Conklin does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate,

then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a clear solution of gamma terpenes and polysorbate 20. The specific amounts of each ingredient would have been determinable by routine experimentation.

26. Regarding Claim 10, Conklin teaches that sunflower oil is contemplated by his invention (Table 1). Sunflower oil is largely linoleic acid triglyceride. The use of linoleic acid trigyceride would have been obvious given this teaching. Conklin also teaches the use of polysorbate 80 as a surfactant (Col. 11, Ex. 5).

27. Conklin does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a

relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a clear solution of linoleic acid triglyceride and polysorbate 20. The specific amounts of each ingredient would have been determinable by routine experimentation.

28. Regarding Claim 15, Conklin teaches that the oils of his invention include ALL "those natural oils normally extracted, as such, from their plant matter or animal source" (Col. 4, Lines 40-45). It would have been obvious to use fish oil as this oil is derived from plant matter, and, as Conklin teaches, any oil derived from plant or animal sources can be used. Fish oil is widely recognized to be an excellent source of omega 3 fatty acids. The person of ordinary skill in the art at the time of invention would realize that fish oil would be oil that is rich in omega 3 fatty acid and also contain animal fats. Therefore, it would have been obvious to have used omega-3 fatty acid. Conklin also teaches the use of polysorbate 80 as a surfactant (Col. 11, Ex. 5).

29. Conklin does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches

that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a clear solution of omega 3 fatty acid containing animal fat and polysorbate 20. The specific amounts of each ingredient would have been determinable by routine experimentation.

30. Regarding Claim 16, Conklin teaches the use of tea tree oil (Table 1). Conklin also teaches the use of polysorbate 20 as a surfactant (Col. 8, Line 12). Conklin does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is

preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a clear solution of tea tree oil and polysorbate 20. The specific amounts of each ingredient would have been determinable by routine experimentation.

31. Regarding Claims 17 and 18, Conklin teaches the use of citral in his invention (Col. 13, Ex. 15). Citral is found in lemongrass which is also contemplated (Table 1). Conklin also teaches the use of polysorbate 20 as a surfactant (Col. 8, Line 12). Conklin does not teach the use of ethanol in the solution. Hirsh however teaches the use of alcohol having one to 6 carbon atoms (Hirsh Claim 12). Ethanol is an alcohol having one to six carbon atoms. It would have been obvious given this teaching to have selected an alcohol such as ethanol.

32. Conklin does not teach the exact ingredient amounts as claimed. To that end, it is important to note that one of the aspects of the present invention that is not claimed is

that the polysorbate and active substances are combined using an excess of polysorbate to give a clear solution (Applicant's specification, Page 2, ¶ 4). Using an excess of polysorbate to create clear emulsions is not a novel concept. Hirsh teaches that to achieve a crystal clear solution of lanolin and polysorbate at least a 7 fold excess of polysorbate 60 is preferred (Hirsh Col. 1, 18-20; Col. 2, Lines 28-32). Furthermore, Hirsh teaches that several types of polysorbate, including polysorbate 20, 40, 60, and 80 were tested and, through experimentation, it was found that polysorbate 60 gave the best result when used in a 7 fold excess (Col.1, Line 68-Col. 2, Line 33). It is apparent, then, from the teachings of Hirsh that the amount and type of polysorbate used bears a relationship to the clarity of solution obtained. The amount and type of polysorbate, then, is a result effective variable. The optimum or workable ranges of result effective variables can be determined by routine experimentation. *In re Antonie,* 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It, therefore, would have been obvious to a person of ordinary skill in the art at the time of invention to have combined the ingredients taught by Conklin with the excess of polysorbate taught by Hirsh to give a clear solution of citral and polysorbate 20. The specific amounts of each ingredient would have been determinable by routine experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH M.J. HANRAHAN whose telephone number is (571) 270-7060. The examiner can normally be reached on M-F from 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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